

REMARKS

In view of the foregoing amendments and the following representations, reconsideration and allowance of the above-identified application is respectfully requested.

Claims 1-12, 15, 16 and 19-23 are pending in the present application.

During preparation of this response, a typographical error was discovered in claim 9. Claim 9 has been amended to correct the typographical error. No new matter is added by the present amendment.

Applicants wish to thank the Examiner for withdrawing the prior rejections under 35 U.S.C. § 112, second paragraph and under 35 U.S.C. § 102(e) in view of Phillips, United States Patent No. 6,645,988.

In the March 13, 2008 Office Action, the Examiner rejected claims 1-12, 15, 16 and 19-23 under 35 U.S.C. § 1032(a) as being unpatentable over Phillips, United States Patent No. 6,645,988 (hereinafter "Phillips") in view of Shimizu et al., United States Patent No. 6,328,994 ("Shimizu").

Applicants respectfully traverse this rejection. Independent claim 1, and all the pending claims which depend on claim 1, recite a multilayered dosage form comprising (a) a proton pump inhibitor layer and (b) an antacid layer. The proton pump inhibitor layer further comprises a proton pump inhibitor granule and a pharmaceutical excipient. The proton pump inhibitor granule comprises (i) a proton pump inhibitor and (ii) a water insoluble film forming polymer, a congeable solid material or a mixture of a water insoluble film forming polymer and a congeable solid material. Claim 1

further recites that the proton pump inhibitor layer is free of acidic film forming polymer and enteric polymers.

Applicants respectfully submit that the pending claims are patentable over the combination of Phillip and Shimizu because the pending claims require a unique proton pump layer that is free of enteric polymers and employs a novel proton pump inhibitor granule. More specifically the proton pump inhibitor granule comprises (i) a proton pump inhibitor and (ii) a water insoluble film forming polymer, a congeable solid material or a combination of a water insoluble film forming polymer and a congeable solid material. This unique proton pump inhibitor granule is not disclosed, explicitly or inherently, in Phillips of Shimizu.

As explained in detail in the December 28, 2007 submission Phillips describes a wide range of potential dosage forms on Col. 14, lines 9-16 but fails to provide any disclosure that would lead an individual of ordinary skill to employ a water insoluble film forming polymer or a congeable solid material in preparation of a proton pump inhibitor granule. The only description of possible excipients appears on Col. 14, lines 24-46 of Phillips. This portion of Phillips does not mention water insoluble film forming polymers or congeable solid materials as required by the pending claims.

The Examiner contends Shimizu teaches the use of proton pump inhibitor granules comprising water insoluble polymers. The Examiner directs Applicants to the disclosure on Col. 13, lines 1-8. This section does not disclose the use of water insoluble polymers. Col. 13, lines 1-8 reads as follows:

controlled by formulating the coat (coating layer) to have different viscosity or content of the **water-soluble polymer** (e.g. HPC, HPMC and so forth) or by formulating the coat to have a controlled ratio of the **ethanol-soluble**

water soluble polymer (e.g., HPC) and the **ethanol-insoluble, water soluble polymer** (e.g. HPMC). The dissolution of the physiological active substance is not very influenced by liquidity, which can be suitably controlled. (emphasis added)

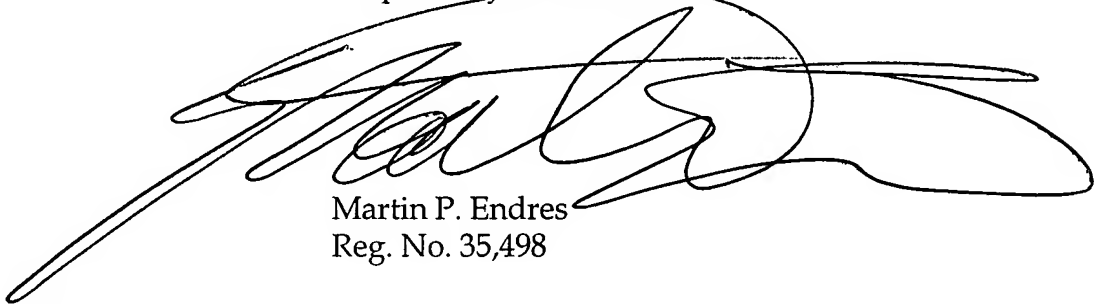
Clearly, the section of Shimizu relied upon by the Examiner only discloses water soluble polymers and NOT water insoluble polymers. The term "insoluble" is only used in reference to ethanol not water. In view of the forgoing, Applicants respectfully submit Shimizu does not overcome the deficiencies of Phillips.

In addition, Applicants respectfully submit the addition of Shimizu to Phillips would lead an individual of ordinary skill away from the presently claimed invention. The present claims recite a proton pump inhibitor layer free of enteric polymers. Shimizu teaches the proton pump inhibitor must be coated with an enteric coating. See Col. 2, lines 56-65; Col. 3, line 14-20 and all working Examples. Therefore, the addition of the Shimizu to Phillips would not lead an individual to the present invention.

In view of Phillips' and Shimizu's complete failure to provide any disclosure or suggestion to employ proton pump inhibitor granules as recited in the pending claims, it is respectfully submitted that the pending claims are patentable over the combination of Phillips and Shimizu.

Based upon the foregoing amendments and representations, Applicants respectfully submit that the rejection of the claims in the above-identified application have been overcome and should be withdrawn. Early and favorable action is earnestly solicited.

Respectfully submitted,

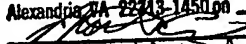


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